Fee Transmittal Form	JAN 2 6 2004  TRANSMITTAL FORM  (to be used for all correspondence after initial  Total Number of Pages in This Submission	5 no persons are required to respond to a collect Application Number  Filing Date First Named Inventor  Art Unit Examiner Name  Attorney Docket Number	PTO/SB/21 (08-0 Approved for use through 08/30/2003. OMB 0651-003 tent and Trademark Office; U.S. DEPARTMENT OF COMMERC ction of information unless it displays a valid OMB control number 10/620,173  July 15, 2003  W.H. ROARK 1614  PC25208A
Firm or Individual name Claude F. Purchase, Jr.  Signature January 16, 2004  CERTIFICATE OF TRANSMISSION/MAILING  I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on	Fee Attached  Amendment/Reply  After Final  Affidavits/declaration(s)  Extension of Time Request  Express Abandonment Request  Information Disclosure Statement  Certified Copy of Priority Document(s)  Response to Missing Parts/ Incomplete Application  Response to Missing Parts	Drawing(s)  Licensing-related Papers  Petition  Petition to Convert to a Provisional Application Power of Attorney, Revocation Change of Correspondence Add  Terminal Disclaimer  Request for Refund  CD, Number of CD(s)	After Allowance communication to Technology Center (TC)  Appeal Communication to Board of Appeals and Interferences Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)  Proprietary Information  Status Letter Other Enclosure(s) (please Identify below): Copies of Cited Art
Typed or printed name  Virginia J. Cook  Signature  Date January 16, 2004	Firm or Individual name Claude F. Purchase, Jr. Signature January 16, 2004  I hereby certify that this correspondence is sufficient postage as first class mail in an er the date shown below.  Typed or printed name Virginia J. Cook	CERTIFICATE OF TRANSMISSIO being facsimile transmitted to the USPTO onvelope addressed to: Commissioner for Province of the Commissi	ON/MAILING or deposited with the United States Postal Service with

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



### PC25208A

### IN THE UNITED STATES PATENT & TRADEMARK OFFICE

APPLICANT: WILLIAM HOWARD ROARK EXAMINER: UNKNOWN

SERIAL NO.: 10/620,173 ART UNIT:

FILED : JULY 15, 2003 CONFIRM. NO. : UNKNOWN

FOR : COMBINATION OF AN ALLOSTERIC ALKYNE INHIBITOR

OF MATRIX METALLOPROTEINASE-13 WITH A

SELECTIVE INHIBITOR OF CYCLOOXYGENASE-2 THAT IS

NOT CELECOXIB OR VALDECOXIB

## INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97-1.98

Commissioner for Patents PO BOX 1450 Alexandria, VA 22313-1450

### Dear Sir:

This paper is an Information Disclosure Statement Under 37 C.F.R. §§ 1.97-1.98 for the above-identified patent application.

Remarks start on page 2.

### **REMARKS**

Claims 1-10 are pending in the application.

The currently pending claims are directed to a combination comprising a selective inhibitor of COX-2 that is not celecoxib or valdecoxib, or a pharmaceutically acceptable salt thereof, and an allosteric alkyne inhibitor of MMP-13, or a pharmaceutically acceptable salt thereof, a pharmaceutical composition comprising the combination, and a method of treating a disease or disorder using the combination. Applicants' instant paper does not amend the claims.

### Information Disclosure Statement

Applicant herein makes available to the Patent and Trademark Office the art cited in the enclosed Information Disclosure Statement ("IDS") on Form(s) PTO/SB/08A and/or PTO/SB/08B. Copies of U.S. patents and patent application publications, if any, cited in the IDS are not provided. Applicant understands that the Patent and Trademark Office has asked that they not be provided in view of their ready availability to the Examiner via electronic means. Copies of all other cited art are provided.

Applicant also makes available to the Patent and Trademark Office the following co-pending applications:

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/620,174

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC INHIBITOR OF MATRIX

METALLOPROTEINASE-13 WITH CELECOXIB OR VALDECOXIB

ART UNIT: UNKNOWN

APPLICANT'S DOCKET NO.: PC25036A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/619,777

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC ALKYNE INHIBITOR OF MATRIX
METALLOPROTEINASE-13 WITH CELECOXIB OR VALDECOXIB

ART UNIT: 1614

APPLICANT'S DOCKET NO.: PC25131A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/619,662

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC CARBOXYLIC INHIBITOR OF
MATRIX METALLOPROTEINASE-13 WITH CELECOXIB OR
VALDECOXIB

ART UNIT: UNKNOWN

APPLICANT'S DOCKET NO.: PC25132A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/619,663

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC INHIBITOR OF MATRIX

METALLOPROTEINASE-13 WITH A SELECTIVE INHIBITOR OF

CYCLOOXYGENASE-2 THAT IS NOT CELECOXIB OR VALDECOXIB

ART UNIT: UNKNOWN

APPLICANT'S DOCKET NO.: PC25207A

APPLICANT: WILLIAM HOWARD ROARK

SERIAL NO.: 10/619,769

FILING DATE: JULY 15, 2003

TITLE: COMBINATION OF AN ALLOSTERIC CARBOXYLIC INHIBITOR OF
MATRIX METALLOPROTEINASE-13 WITH A SELECTIVE INHIBITOR OF
CYCLOOXYGENASE-2 THAT IS NOT CELECOXIB OR VALDECOXIB

ART UNIT: 1614

### APPLICANT'S DOCKET NO.: PC25209A

The Examiner is respectfully requested to consider carefully the complete text of the cited references in connection with the examination of the above-identified application in accord with 37 CFR §1.104(a), including consideration of the claims.

It is respectfully requested that all cited references considered by the Examiner be listed in the "References Cited" portion of any patent issuing from the instant application (MPEP § 1302.12).

The Commissioner is hereby authorized to charge any other fees that may be required, or credit any overpayment, to deposit account number 23-0455.

The undersigned would welcome a telephone call from the Office to discuss any matters.

Respectfully submitted,

Date: January 16, 2004

Claude F. Purchase, Jr.

Reg. No. 47,871

Warner-Lambert Company

2800 Plymouth Road

Ann Arbor, MI 48105

Tel. (734) 622-1692 Fax (734) 622-1553

Enc.

JAN 2 6 2004 Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Sheet 1

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Con	nplete if Known
Application Number	10/620,173
Filing Date	July 15, 2003
First Named Inventor	W. H. Roark
Art Unit	1614
Examiner Name	
Attorney Docket Number	PC25208A

Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
Initials*	No. <sup>1</sup>	Number-Kind Code <sup>2 (# known)</sup>	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
		<sup>US-</sup> 2003/0078276 A1	04-24-2003	ANDRIANJARA, ET AL	
		<sup>US-</sup> 2003/0130278 A1	07-10-2003	GAUDILLIERE, ET AL	
		<sup>US-</sup> 2003/0144274 A1	07-31-2003	BUNKER, ET AL	
		<sup>US-</sup> 6008243	12-28-1999	BENDER, ET AL	
		<sup>US-</sup> 5948780	09-07-1999	PETERSON, ET AL	-
		<sup>US-</sup> 2002/0156061 A1	10-24-2002	BARVIAN ET AL	
		<sup>US-</sup> 2002/0151558 A1	10-17-2002	ANDRIANJARA, ET AL	
		<sup>US-</sup> 2002/0156069 A1	10-24-2002	PICARD ET AL	
		<sup>US-</sup> 2002/0151555 A1	10-17-2002	BARVIAN ET AL	
		<sup>US-</sup> 2002/0161000A1	10-31-2002	BARVIAN ET AL	
		<sup>US-</sup> 6225311 B1	05-01-2001	LEVIN ET AL	
		<sup>US-</sup> 5929097	07-27-1999	LEVIN ET AL	
		<sup>US-</sup> 4818819	04-04-1989	E.C. TAYLOR ET AL	
		<sup>US-</sup> 4902796	02-20-1990	E.C. TAYLOR ET AL	
		<sup>US-</sup> 5646141	07-08-1997	M.D. VARNEY ET AL	
		<sup>US-</sup> 4412856	11-01-1983	BRUNNER ET AL	
		<sup>US-</sup> 5990116	11-23-1999	NUSSBAUMER	
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	FORE	IGN PATENT DOCL	MENTS		
 Cite No.1	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
 	Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	Τ°
	WO 03/032999 A1	04-24-2003	BUNKER ET AL		
	WO 03/033478 A1	04-24-2003	GAUDILLIERE ET AL		
	WO99/52910 A1	10-21-1999	ROBINSON, Ralph		
	WO 00/37107 A2	06-29-2000	MCKEARN ET AL		
	WO 02/064080 A2/A3	08-22-2002	ANDRIANJARA ET AL		
	WO 00/09485 A1	02-24-2000	MCCLURE ET AL		Γ

Examiner	Date	
Signature	Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Coi	Complete if Known				
Application Number	10/620,173				
Filing Date	July 15, 2003				
First Named Inventor	W.H. Roark				
Art Unit	1614				
Examiner Name					
Attorney Docket Number	PC25208A				

Examiner	Cite Document Number		U. S. PATENT DO	Name of Patentee or	Pages, Columns, Lines, Where
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	WO0155133 A1	08-02-2001	WATANABE ET AL		
	WO0206513 A2	01-24-2002	HOMA ET AL		Г
	WO9616046 A2/A3	05-30-1996	GUERRY ET AL		Г
	WO0040561 A1	07-13-2000	TURNER ET AL		T
	WO9816514 A1	04-23-1998	LEVIN ET AL		
	Cite No.1	Cite No.1  Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)  WO0155133 A1  WO0206513 A2  WO9616046 A2/A3  WO0040561 A1	Cite No.1         Foreign Patent Document         Publication Date MM-DD-YYYY           Country Code3 Number 1 Kind Code3 (if known)         08-02-2001           WO0155133 A1         08-02-2001           WO0206513 A2         01-24-2002           WO9616046 A2/A3         05-30-1996           WO0040561 A1         07-13-2000	Cite No. 1         Foreign Patent Document         Publication Date MM-DD-YYYY         Name of Patentee or Applicant of Cited Document           WO0155133 A1         08-02-2001         WATANABE ET AL           WO0206513 A2         01-24-2002         HOMA ET AL           WO9616046 A2/A3         05-30-1996         GUERRY ET AL           WO0040561 A1         07-13-2000         TURNER ET AL	Cite No. 1         Foreign Patent Document         Publication Date MM-DD-YYYY         Name of Patentee or Applicant of Cited Document         Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear           WO0155133 A1         08-02-2001         WATANABE ET AL           WO0206513 A2         01-24-2002         HOMA ET AL           WO9616046 A2/A3         05-30-1996         GUERRY ET AL           WO0040561 A1         07-13-2000         TURNER ET AL

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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of 8

Col	mplete if Known	
Application Number	10/620,173	
Filing Date	July 15, 2003	
First Named Inventor	W.H. ROARK	
Art Unit	1614	
Examiner Name		
Attornay Dooket Number	DC25200A	

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Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	WO0035906 A2	06-22-2000	LUK ET AL		
	WO0163244 A1	08-30-2001	CHEN ET AL		
	WO02064599 A1	08-22-2002	DYER ET AL		
	WO02064547 A2/A3	08-22-2002	BARVIAN ET AL		
	WO02064598 A1	08-22-2002	HARTER ET AL		
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\*EXAMINE: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

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Coi	mplete if Known	
Application Number	10/620,173	
Filing Date	July 15, 2003	
First Named Inventor	W.H. ROARK	
Art Unit	1614	·····
Examiner Name		
Attornov Docket Number	DC25200A	

			U. S. PATENT D	OCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>5</sup> ( <i>if known</i> )	MM-DD-YYYY		Or Relevant Figures Appear	T⁰
		WO02064572 A1	08-22-2002	ANDRIANJARA ET AL		
		WO02064595 A1	08-22-2002	ANDRIANJARA ET AL		
		WO02064578 A1	08-22-2002	PICARD ET AL		
		WO02064571 A1	08-22-2002	BARVIAN ET AL		
		WO02064568 A1	08-22-2002	BARVIAN ET AL		
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Sheet 5

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Complete if Known		
Application Number	10/620,173	
Filing Date	July 15, 2003	
First Named Inventor	W.H. ROARK	
Art Unit	1614	
Examiner Name		
Attorney Docket Number	PC25208A	

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		FORE	IGN PATENT DOCL	JMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	▎ᢚ
		WO0234726 A3/A2	05-02-2002	NOE ET AL		
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-Substitute for form 1449/PTO

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Sheet 6

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known			
Application Number	10/620,173		
Filing Date	July 15, 2003		
First Named Inventor	W.H.ROARK		
Art Unit	1614	•	
Examiner Name			
Attorney Docket Number	PC25208A		

			U. S. PATENT D	OCUMENTS	
Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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		Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>3</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T
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Examiner	Date	
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- Oupside	0 101 101111 144011 10			Application Number	10/620,173	
INFO	DRMATION	DIS	CLOSURE	Filing Date	July 15, 2003	
STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	W. H. Roark	
(Use as many sheets as necessary)			ocasean/i	Art Unit	1614	
			ecessary)	Examiner Name		
Sheet	7	of	8	Attorney Docket Number	PC25208A	

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Complete if Known Substitute for form 1449/PTO **Application Number** 10/620,173 INFORMATION DISCLOSURE Filing Dat July 15, 2003 STATEMENT BY APPLICANT **First Named Inventor** W.H. Roark Art Unit 1614 (Use as many sheets as necessary) **Examiner Name** Attorney Docket Number Sheet 18 of 8 PC25208A

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